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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,537	12/11/2001	Bettina Moeckel	203973US0X	7853

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EXAMINER	
FRONDA, CHRISTIAN L	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/867,537	MOECKEL ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- Th MAILING DATE of this communication appears on th cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-32,34,36-38 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-32,34,36-38 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/16/01, 11/20/01
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 26-32, 34, 36-38, and 47 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 26-32, 34, 36-38, and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 10/28/2003 have been fully considered but they are not persuasive. Applicants' position is that the specification provides support for making the claimed invention including using a weak promoter, using a gene or allele which codes for a corresponding enzyme with a low activity, or using an allele that inactivates the corresponding gene or enzyme. The Examiner respectfully disagrees for reasons of record as supplemented below.

The claims are directed to any attenuated lysR3 gene of any nucleotide sequence and structure made by any genetic modification where prior to being attenuated comprises SEQ ID NO: 1, SEQ ID NO: 3, or a polynucleotide which hybridizes under stringent hybridization conditions to the full complement of SEQ ID NO:1 or SEQ ID NO: 3 and encodes a protein with LysR3 transcriptional regulatory activity.

The claims are directed to a genus of nucleotide sequences which is expected to vary in sequence and structure made by any genetic modification which results in an attenuated expression of the lysR3 gene in any bacterial cell for use in the production of L-amino acids. The claim as amended does not limit the claimed invention to an invention that is adequately described by the specification. The specification describes only one genetic modification to achieve an attenuated lysR3 gene where a 323bp fragment of SEQ ID NO: 1 ("lysR3 gene") is integrated into a coryneform bacterium. The specification states that this 323bp fragment is SEQ ID NO: 3.

The specification does not provide a written description of the genus of nucleotide sequences as encompassed by the claims which is expected to vary in sequence and structure made by any genetic modification which results in an attenuated expression of the lysR3 gene in any bacterial cell. Furthermore, claims 36, 37, and 38 are directed toward enhanced genes dapA, eno, zwf, pyc, lysE, ilvBn, ilvD, and mqo or attenuated genes pck, pgi, and poxB which is not described by the specification since the claim is a genus claim that encompasses genes that are expected to vary in sequence and structure made by any genetic modification which results in an enhanced expression of the gene in any bacterial cell.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

4. Claims 26-32, 34, 36-38, and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing L-amino acids by culturing a transformed/recombinant bacterial cell comprising an inactivated lysR3 gene consisting of the nucleotide sequence of SEQ ID NO: 3; does not reasonably provide enablement for any other embodiment.

Applicants' arguments filed 10/28/2003 have been fully considered but they are not persuasive. Applicants' position is that the specification provides support for making the claimed invention and define the lysR3 gene prior to attenuation as comprising SEQ ID NO: 1, 3, or a polynucleotide that hybridizes to the complement of SEQ ID NO:1 or SEQ ID NO: 3 and encodes a protein with LysR3 transcriptional regulatory activity. The Examiner respectfully disagrees for reasons of record as supplemented below.

The claims encompass any method for producing L-amino acids by culturing any bacterial cell comprising any attenuated lysR3 gene of any nucleotide sequence and any genetic modification which results in the activity of the lysR3 protein being reduced or eliminated. The specification provides guidance and examples for a method for producing L-amino acids by culturing a transformed/recombinant bacterial cell comprising an inactivated lysR3 gene consisting of the nucleotide sequence of SEQ ID NO: 3. However, the specification does not teach the nucleotide sequence of any LysR3 gene from any biological source and any genetic modification which results in the activity of the lysR3 protein being reduced or eliminated.

The amount of experimentation to make the claimed bacterial cell comprising any attenuated lysR3 gene of any nucleotide sequence and any genetic modification which results in the activity of the lysR3 protein being reduced or eliminated for use in the production of L-amino acids is undue and enormous. The experimentation entails screening a vast number of organisms for a biological source which contains any lysR3 gene of any nucleotide sequence, performing any genetic modification which results in the activity of the lysR3 protein being reduced or

eliminated, and screening for mutant lysR3 proteins which have reduced or no protein activity.

Searching for the specific biological source and specific mutation is well outside the realm of routine experimentation and predictability in the art of success is extremely low since no information is provided by the specification regarding the specific nucleotide sequence of any lysR3 gene and any genetic modification which results in the activity of the lysR3 protein being reduced or eliminated for use in the production of L-amino acids. Thus, the specification does not provide enablement for the full scope of the claimed invention.

Conclusion

5. No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (571)272-0929. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571)272-0928. The offical fax phone number (703)872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571)272-1600.

CLF

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